CLRES/MEDEDU 2050
Ethics and Responsible Conduct of Researc
Dates: Spring Term
Location: Parkvale 305

Overview and Objectives:

This course aims to enhance students' ability to think about 1) the ethical dimensions of research, especially research involving human subjects and 2) the responsible conduct of research, including an understanding of the obligation to adhere to regulations and conform to accepted practices to ensure research quality and integrity.

Responsibilities:

Knowledge:

By the end of the course, students should be able to:

- Describe the historical context for today's heightened scrutiny of the ethics of clinical research and scientific integrity.
- Identify and explain the basic concepts, values, and potential ethical conflicts associated with the conduct of human subjects research.
- Define the elements of scientific misconduct.

Attitudes:

By the end of the course, students should be able to:

- Demonstrate a commitment to integrity in the conduct of scientific research.
- Demonstrate a commitment to advocate for the rights and welfare of human research subjects.

Skills:

By the end of the course, students should be able to:

- Analyze case examples of clinical research and scientific integrity according to ethical criteria.
- Explain a scientific research protocol in language that promotes laypeople's understanding sufficient to provide meaningful informed consent.
- Demonstrate communication skills adequate to obtain a potential research subject's meaningful informed consent.
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Course Requirements:

- **Active participation in class discussions and exercises.**

- **Two 4-page, double-spaced essays analyzing ethical aspects of cases in clinical research and scientific integrity.**

- **Participation in a role- playing exercise for informed consent conversations (Session 7).** Participation in the role-play session is required for all students, in either the live or on-line versions of the course. Students will conduct an informed consent conversation with a trained actor who will be simulating a potential subject for the student's research. Students will attempt to enroll the "subject" in their own clinical or translational research project—either a project they are currently engaged in, or one that they are developing as part of their research training. After the role-play, students will receive feedback on their communication skills from the actor and from fellow students who will observe the role-play.
- **Students who do not have a clinical or translational research project of their own that is suitable for the role play** will participate in the class as **observers.** They will provide valuable

feedback to their role-playing colleagues, using a feedback form provided in class.

Attendance Policy:
Students are expected to sign-in to each class (computer provided in suite lobby). If a problem is encountered with the sign-in system, please contact the course instructor(s) as well as Lauren Talotta (talottals@upmc.edu) immediately.

Course Grading Scale:
The final grade for the course will be based on the following point values for the required assignments:

For students PARTICIPATING DIRECTLY in the informed consent role playing exercise in Session 7:

Essay #1: 35 points
Essay #2: 35 points
Participation in class discussion: 15 points
Role playing exercise: 15 points

For students NOT participating directly in the informed consent role playing exercise in Session 7, but providing feedback as OBSERVERS:

Essay #1: 40 points
Essay #2: 40 points
Participation in class discussion: 15 points
Observation of role-play: 5 points

Textbooks:
Ezekiel Emanuel, et al, eds. *The Oxford Textbook of Clinical Research Ethics*. New York: Oxford University Press, 2008.
Francis L. Macrina, *Scientific Integrity*. 3rd ed. Washington, DC: ASM Press, 2005.

Website resources:
http://courseweb.pitt.edu/

Academic Integrity:
Students in this course will be expected to comply with the University of Pittsburgh's Policy on Academic Integrity (http://www.provost.pitt.edu/info/ai1.html). Any student suspected of violating this obligation for any reason during the semester will be required to participate in the procedural process, initiated at the instructor level, as outlined in the University Guidelines on Academic Integrity. This may include, but is not limited to, the confiscation of the examination of any individual suspected of violating University Policy. Furthermore, no student may bring any unauthorized materials to an exam, including dictionaries and programmable calculators.

Course Schedule

Session 1: **1. Course overview and ethical frameworks for clinical research**
2. Ethical aspects of randomized controlled trials
3. RCR Survey*

At the conclusion of this class, the student will be able to:

- Appreciate the historical antecedents to contemporary regulation of clinical research.

- Identify potential value conflicts in the conduct of medical experimentation with human beings.
- List eight principles for ethical clinical research.
- Describe the criteria applied by the IRB to the ethical evaluation of research protocols.
- List the range of ethical issues that are raised by RCTs.
- Define "clinical equipoise" and explain its importance to the decision to initiate or terminate an RCT.
- State ethical arguments in favor of and against the use of placebos in an RCT when an active treatment is available for the condition under study.

Required Readings:

Emanuel:
Chapter 8: "The Tuskegee Syphilis Experiment"
Chapter 10, "The Gelsinger Case"
Chapter 11, "An Ethical Framework for Biomedical Research"
Chapter 24, "Equipoise and Randomization"

* The textbook by Macrina contains in Appendix 1 a survey of trainees' experiences or observations of scientific misconduct. The survey includes 29 items, which we will ask all students in the course (in both the live and on-line versions) to answer via an on-line survey instrument. In **Session 2** of the course we will divide the students into groups of approximately 4 or 5 students. Each group will be assigned a set of questions from the survey, and will analyze the results of the survey for those questions, picking out trends, interesting findings, and the like. In **Session 3**, the student groups will present their findings to the class through PowerPoint and group discussion.

Session 2: **1. Overview and ethical frameworks for scientific integrity and RCR**
2. Mentoring
3. Assign student groups to analyze survey results

At the conclusion of this class, the student will be able to:

- Name and discuss the four areas that are the focus of RCR
- Define scientific misconduct
- Explain some of the implications of scientific misconduct for society
- Delineate responsibilities of mentor and mentee with respect to RCR

Required Readings:

Macrina:
Chapter 1: "Methods, Manners, and the Responsible Conduct of Research"
Chapter 3: "Mentoring"
Pitt Research Misconduct Policy
Nicholas H. Steneck, ***ORI Introduction to the Responsible Conduct of Research,*** Parts I (pp. 1-29) and V (pp. 160-164). Available at Introduction to the **Responsible Conduct of Research**
ori.hhs.gov/documents/rcrintro.pdf

Session 3: **1. Discuss survey results (see explanation under Session 1, above)**
2. Research misconduct (falsification, fabrication, plagiarism)
3. Conflicts of interest

At the conclusion of this class, the student will be able to:

- Define "research misconduct," "plagiarism," "conflict of interest," "conflict of commitment,"

"fraud," "fabrication," and "falsification" in the research context.
- Recognize potential "conflicts of interest" and "conflicts of commitment" in the conduct of scientific research.
- Analyze policies that have been proposed to eliminate or manage conflicts of interest in research.

Required Readings:

Macrina:
Chapter 7: "Managing Competing Interests"
Additional readings on "Fraud":
Goodstein, D. "Scientific Fraud." *American Scholar*, 1991, 60:505-515
Schachman, HK. "What is Misconduct in Science?" *Science,* 1993, 261:148-149

Session 4: **1. Authorship and peer review**
2. Data management
3. Collaborative research
4. Role play authorship discussion from Macrina text*

At the conclusion of this class, the student will be able to:

- Describe why authorship consideration is a significant aspect of RCR.
- Negotiate appropriate authorship credit for a collaborative publication.
- Delineate considerations about when one should obtain a patent, copyright, or otherwise protect research.
- Describe some procedures to ensure integrity and authenticity of data.
- Describe NIH's stance on the sharing of data and the reasons for this stance.
- Define nine principles of effective collaboration.

Required Readings:

Macrina:
Chapter 4: "Authorship and Peer Review"
Chapter 8: "Collaborative Research"
Chapter 9: "Ownership of Data and Intellectual Property"
Chapter 11: "Scientific Record Keeping"

* The textbook by Macrina contains in Appendix 2 a role play script on the subject of authorship. In the script, the members of a research group are discussing among themselves the placement in the list of authors for a forthcoming manuscript that each member believes is appropriate, given his or her role in the underlying research. For the role play, each student will take one of the parts in the script, which will include a description of what that character did for the research project. On that basis, the student will argue for the appropriate authorship credit. The other students in the role play will be encouraged to challenge (respectfully) their fellow students' assertions of entitlement to authorship credit with which they disagree.

Session 5: **Human subjects research with vulnerable populations**

At the conclusion of this class, the student will be able to:

- Analyze the concept of "vulnerability" as it relates to potential subjects of clinical research.
- Describe criteria for the ethical inclusion of people with impaired decision-making capacity or children in clinical research.
- Define "decision-making capacity" in clinical and research settings.

. **Required Readings:**

Emanuel:
Chapter 41: "Research Involving Those at Risk for Impaired Decision-Making Capacity"
Chapter 42: "Research With Children"

Session 6: Informed consent

At the conclusion of this class, the student will be able to:

- Identify the ethical foundations of informed consent.
- List three necessary conditions for valid informed consent to participate in a biomedical research study.
- List the elements of informed consent to participate in a biomedical research study.
- Define the therapeutic misconception and explain why it is a common occurrence in enrolling subjects in randomized clinical trials.
- Distinguish between consent as the signing of a form and consent as the result of a process of dialogue between investigator and subject.
- Describe and apply criteria of appropriate advertisements seeking participants for research studies.

Required Readings:

Emanuel:
Chapter 56: "Philosophical Justifications of Informed Consent in Research"
Chapter 37: "Recruiting Research Participants"

Session 7: Role playing informed consent conversations (4 hour session)

At the conclusion of this class, the student will be able to:

- Identify positive and negative communications behaviors in videotaped informed consent conversations
- Demonstrate communication skills adequate to obtain a potential research subject's meaningful informed consent.

This class session, for which attendance in person is required for students in both the live and on-line sections of the course, will last for four hours and will have the following components:

1. (One hour)

Students will divide into three groups. Each group will view a videotaped informed consent conversation between an oncologist who is seeking subjects for a clinical trial and a 65-year-old African American man who has recently been diagnosed with inoperable bladder cancer. The videotape will portray the conversation twice. For each version, the group will identify and discuss positive and negative aspects of the physician's communication behavior, both from the point of view of informed consent, and from the point of view of the recruitment of minority populations in clinical research. Students will be invited to suggest and demonstrate alternative approaches to the conversation.

2. (Three hours)

Students with appropriate clinical or translational research projects will role play an informed consent conversation with an actor trained to simulate a potential study participant. Actors will portray potential participants of varied socio-economic, educational, ethnic, and cognitive status, matched as closely as possible to the likely study populations for the students' projects. Students will receive feedback from the actor and from fellow students, and will have the opportunity to try alternative conversational approaches to incorporate this feedback.